

SIEMENS

SIREMOBIL Compact

SP

DHHS Maintenance Instructions

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English

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To ensure compliance with the applicable provisions of the Federal Performance Standard, the user of the equipment has to ensure that the maintenance procedure described below is performed at intervals of six months or less. In case the user does not comply with these requirements, the manufacturer can no longer be held liable.

If the results of any of the tests described in this document exceed the tolerances given, the required adjustments must be performed.

Contact Siemens service.

After performing any adjustment, all applicable tests must be repeated.

Customer:	Customer No.:	Room:
BZ-No.:	Type No.:	Serial No.:

After completion of maintenance:

I hereby certify that all procedures described in these maintenance instructions have been completed as specified and that the tolerance values are within the accepted range.

Date

Signature

1 Required reference documents

- DHHS Test certificate 1a+ and Acceptance Test Protocol
(in Register 3 of the Logbook)

2 Required test equipment

- | | | |
|--------------|-------------------|---------------------------|
| - PTW-Nomex | Serial-No.: | Date of calibration |
| - Fluke | Serial-No.: | Date of calibration |
| - Calculator | | |

3 Safety Notes

CAUTION

All local safety regulations must be observed.

4 Notes for the Maintenance Instructions

- Compliance with the applicable sections of the Federal Performance Standards is assured when all procedures described in these instructions have been performed and tolerance values are within the specified range.
- The unit movements required for these procedures must be performed cautiously to prevent the unit from being damaged in the event of a malfunction.

**WARNING**

Checks or adjustments to be performed with radiation ON are marked with the radiation warning symbol .

- When performing safety checks or adjustments with radiation ON, radiation protection clothing must be worn.

1 Radiation protection

Make sure that there is no mechanical damage on the SIREPHOS tube housing assembly and image intensifier which could impair the radiation protection.

SIREPHOS and image intensifier
have been checked for mechanical
damage

☐ YES

☐ NO

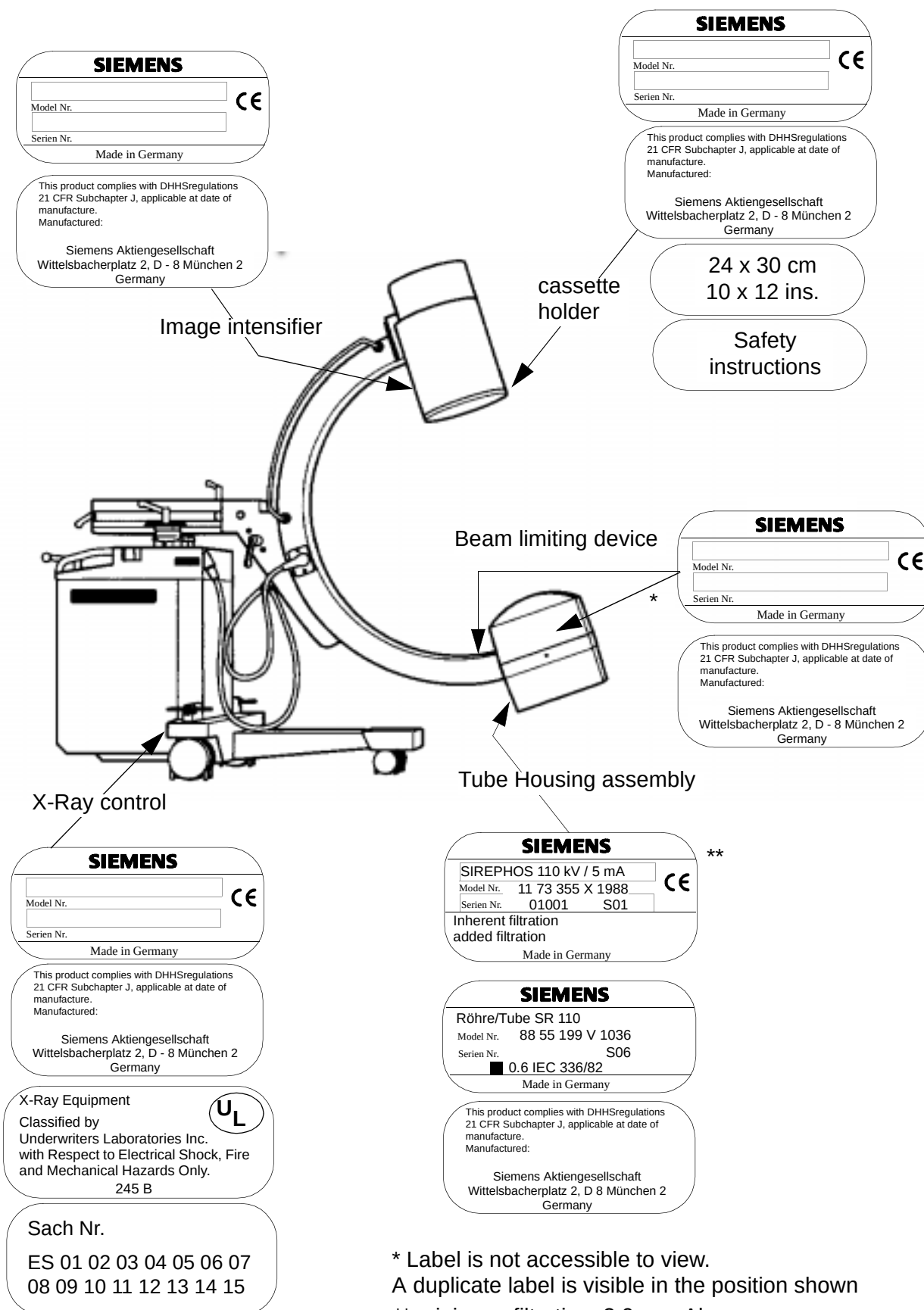
Damage present (brief description):

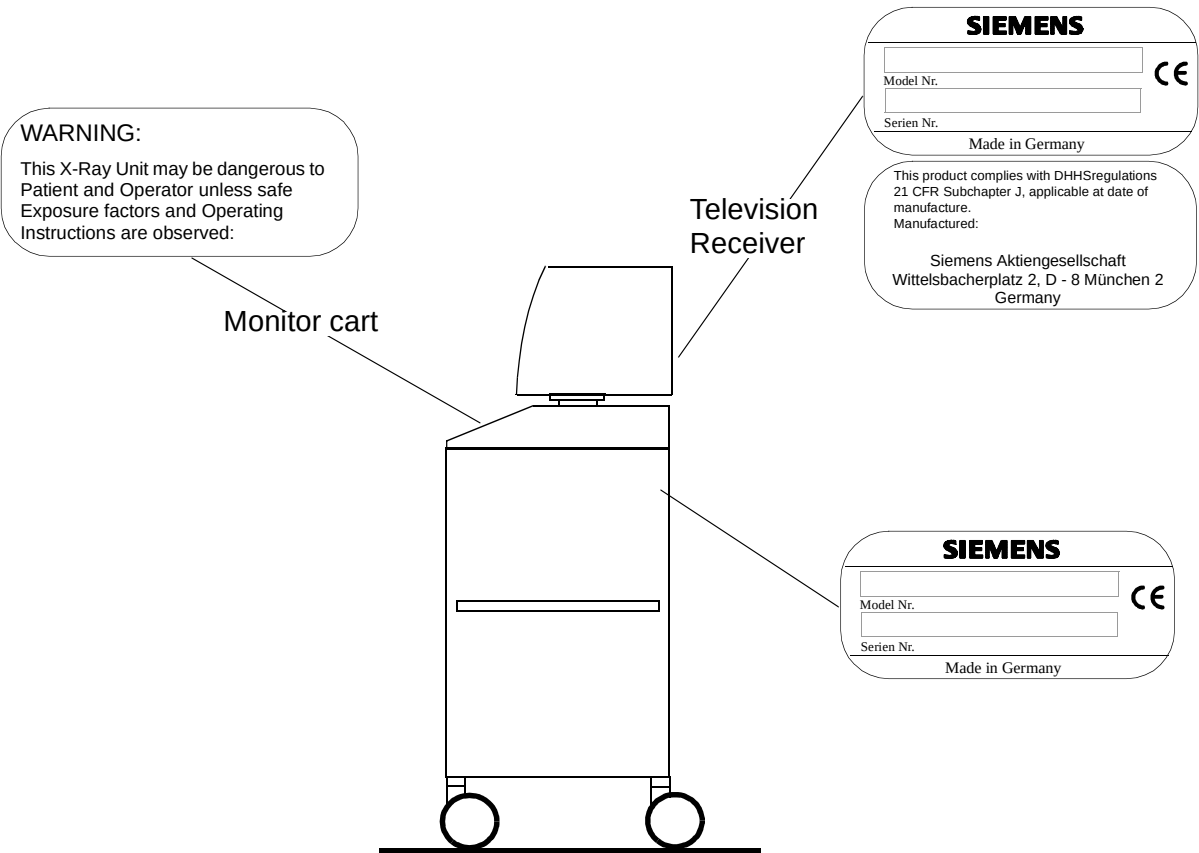
2 Checking the DHHS and Identification Labels

Confirm that the certification labels as well as serial number and model number labels are legible. The illustration shows the location of the labels.
If labels are required, contact the Regulatory Affairs department in Iselin, N.J.

Component certified	Model No.	Serial No.	Date
SIREMOBIL Compact X-ray control			
Beam Limiting device BLD			
Cassette holder (if present)			
SIREPHOS Compact Tube housing assembly			
Image Intensifier			
Television receiver			
Warning label present and legible			☐ YES

2.1 Location of the DHHS and Identification Labels





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1 Checking the "deadman" switch function

1.1 Exposure



An exposure value is set at the control console.

- Activate the exposure with the exposure switch and end it immediately by releasing the switch.
The exposure must end immediately.

1.2 Fluoroscopy



Activate fluoroscopy for a short time and release the fluoroscopy switch.
Fluoroscopy must stop immediately.

- a) with the fluoroscopic switch at the control console
- b) with the foot switch

Deadman's switch is functioning	☐ YES	☐ NO
---------------------------------	------------------------------	-----------------------------

2 Radiation indicators



Check that the radiation indicators at the control console and on the monitor cart are visible during radiation and that an audible (whistling) signal is sounded after exposure release for about 1.5 seconds.

Radiation indicators are functioning	☐ YES	☐ NO
--------------------------------------	------------------------------	-----------------------------

3 Fluoroscopy timer



1. Ensure that the people present are not subject to radiation hazard during the tests described below.
2. Set the manual fluoroscopy voltage to the lowest possible kV value.
Close the Iris diaphragm, cover the tube assembly with a lead apron.
3. Switch on fluoroscopy.
4. Check that the acoustic signal sounds after a total fluoroscopy time of 4.5 minutes has elapsed.
5. Reset the buzzer by pressing the button under the symbol 🔔 in the display.

Fluoroscopy timer functioning correctly	☐ YES	☐ NO
---	------------------------------	-----------------------------

4 Indication of X-ray tube potential and current



Confirm that tube potential and current are continuously indicated during fluoroscopy.

Indicators functioning	☐ YES	☐ NO
------------------------	------------------------------	-----------------------------

5 Minimum source to skin distance

Confirm that a spacer limiting the source to skin distance (SSD) to 30 cm is present.

Spacer present	☐ YES	☐ NO
----------------	------------------------------	-----------------------------

1 Checking the accuracy of the tube voltage

The actual kV value must agree with the indicated value within the limits stated by Siemens (max. deviation $\pm 10\%$ for the Siremobil Compact), if the X-ray system is connected to a power supply corresponding to Siemens specifications.

Tools: PTW-Nomex

Test procedure:

Refer to the information on the Nomex in the operating instructions

Connect the Nomex.

Remove the single-tank cap at the SIREPHOS after removing the two screws.

Select full image intensifier format and open the collimator fully.

Place the measuring detector on the diaphragm.

Set the following values in the operating field and check

Operating mode	Indicated	Measured	Tolerance
Fluoroscopy	70 kV		63 kV to 77 kV
Fluoroscopy	101 kV		91 kV to 110kV
Fluoroscopy	110 kV		100 kV to 120 kV
Radiography	102 kV		92 kV to 110kV

2 Reproducibility

The coefficient of variation must not exceed 0.05 when the X-ray system is connected to a power supply as specified by Siemens.

The technique factors should be adjusted to alternate settings and reset to the test setting after each measurement.

2.1 Measurement set-up

Place the dosimeter in the center of the X-ray beam.

Before each new dose measurement, make sure that the indicator is reset to zero.



2.2 Calculations

Variation coefficient C

For n individual measurements, the coefficient of variation C amounts to:

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}} \left[\sum_{i=1}^n \frac{(x_i - \bar{x})^2}{n-1} \right]^{1/2}$$

s = calculated standard deviation

$\bar{x}$ = mean value of all individual measurements

x_i = measured value of the ith measurements.

1. To obtain the average x, the 4dose values are added and the sum is divided by 3.
2. To obtain the difference, the average value is subtracted from each individual measured value and entered into the column provided

Measurement	Radiation Exposure (x_i)	Average ($\bar{x}$)	= Difference*
1			
2			
3			
4			
* Disregard the sign if negative numbers are obtained.			

Square the differences

Measurement	Square of the difference ($(x_i - \bar{x})^2$)
1	
2	
3	
4	

3. Add the 4results: Σ
4. Divide the sum by 3:
5. Obtain the square root of the new result: Square root S:
6. Divide the square root S by the average value x determined in step 1:

$$\text{Coefficient of variation } C = \frac{S}{\bar{x}} \quad C = \dots\dots\dots \text{ (must be } \leq 0.05)$$

3 Entrance exposure rate

The legal maximum entrance exposure rate is 87 mGy/min (10 R/min).

For safety reasons, the value has been fixed at < 78 mGy/min (9 R/min) at the factory.

The entrance exposure rate is to be checked by means of a dose rate meter.

In the measurement setup shown, the maximum adjustable values 110 kV and 5 mA yield an input dose rate of approx. 87mGy/min (10 R/min).

Measurement set-up

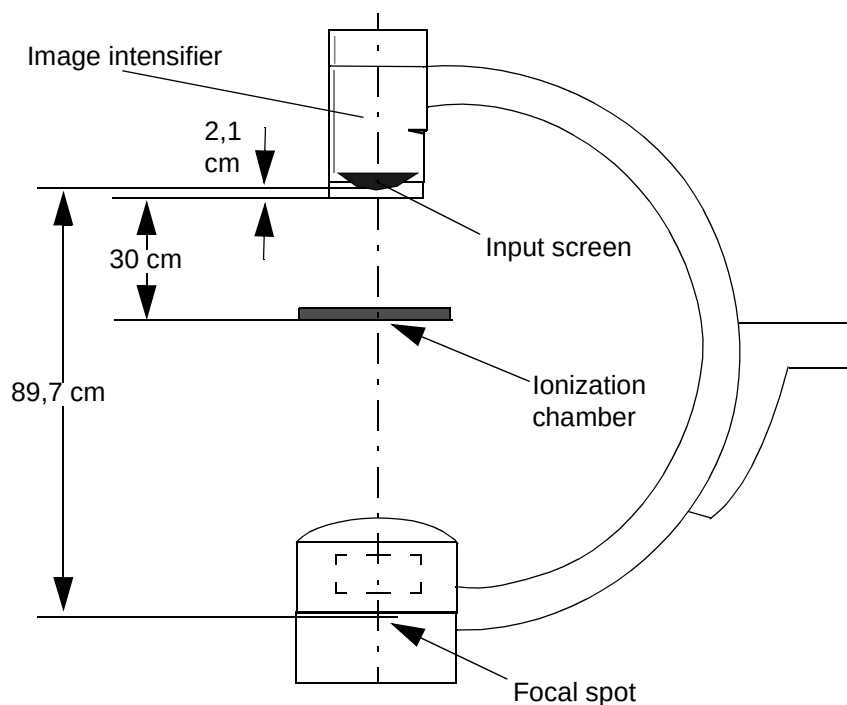


Fig. 1



Position the measurement detector of the dosimeter as shown in the diagram.

Press the "⊕" button at the operating console.

Select 110 kV. Select full I.I. format, open the collimator to max. aperture, switch fluoroscopy "ON". Measure the dose and record.

4 Checking the central beam

REGULATION - Means must be available whereby the radiation field can be centered in relation to the radiation receiver within a tolerance of less than 2 % of the SID.

4.1 Position of central beam in relation to the I.I. input

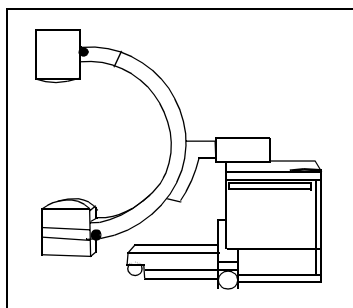
The check is made at the TV monitor.

Determine the central point at the I.I. input. Use adhesive tape to attach center cross (with lead ruler).

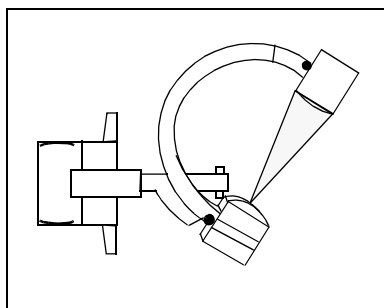
Open the slot collimator, adjust the iris diaphragm to an opening of about 15 cm.

Perform the test in the C-arm position shown.

Basic position



C-arm to the left
(top view)



C-arm to the right
(top view)

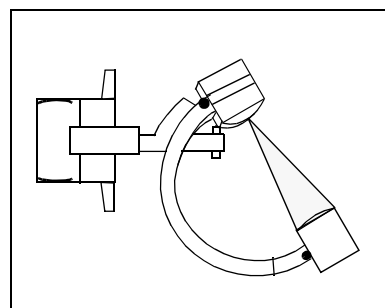


Fig. 2

A = mid-point I.I. input
B = middle of the radiation field
 Δ = deviation of A to B
x = deviation in the x-axis
y = deviation in the y-axis

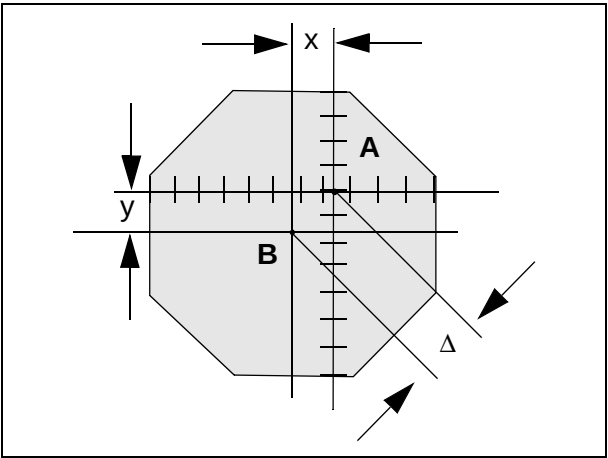


Fig. 3

Work sequence:

1. Select full size (no zoom).
2. Adjust the Iris diaphragm to an opening of about 15 cm.
3. Adjust C-arm (see Fig. 2).
4. Read the evaluation at the TV Monitor (Fig. 3).
(Use stored image if available).
5. Switch on fluoroscopy
6. Calculate the deviation

$\Delta : \sqrt{x^2 + y^2}$

7. Test result (see also Fig. 3):

Average deviation	Δ	permissible*	Average deviation actual
Basic position	Δ	= must be 17 mm (2% of the SID)	 mm
C-arm to the left	Δ	= must be 17 mm (2% of the SID)	 mm
C-arm to the right	Δ	= must be 17 mm (2% of the SID)	 mm



5 Check the I.I. format

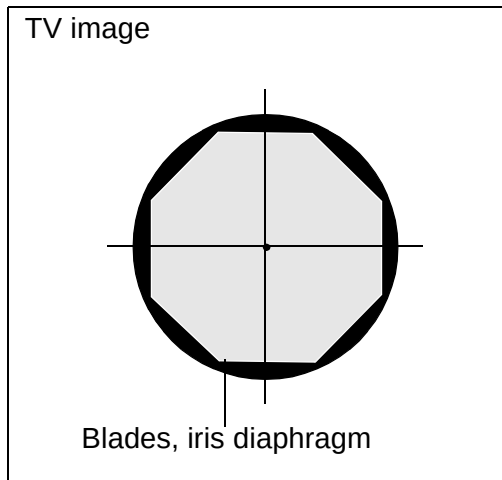


Fig. 4

During fluoro, neither the length nor the width of the radiation field in the plane of the image receptor may exceed that of the visible area of the image receptor by more than 3 % of the SID (focus - I.I. distance). The sum of the longitudinal deviation X and the width deviation Y shall be no greater than 4 % of the

Work sequence:

1. Select the full I.I. input format.
2. Set the iris diaphragm to max. aperture
3. Switch on fluoroscopy
If all eight blades of the iris diaphragm are still visible at the edge of the TV monitor (Fig. 4), no further tests are necessary.
4. Select zoom format (check as in item 3)..

I.I. format in order

☐ YES

☐ NO

Zoom format in order

☐ YES

☐ NO

6 Check the smallest field size

The smallest field size should be max. 5 cm x 5 cm at the I.I. input.

The check is made at the TV monitor.

1. Select full I.I. view format.
2. Close the iris diaphragm and select full I.I. view format.
3. Attach a center cross with lead ruler to the center of the I.I. input screen.
4. Switch on fluoroscopy.
5. Read the size of the X iris on the monitor.

Smallest field size at the I.I. input: cm x cm

7 Cassette format

(Only applicable if cassette holder present)

If no cassette is inserted, continuous fluoroscopy is selected.

Exposure release need not be blocked.

Neither the length nor the width of the X-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than 3 percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum (disregarding the sign) of the length and width deviations may not exceed 4 % of the SID.

The cassette format is limited by means of the rectangular diaphragm.

7.1 Cassette to radiation field

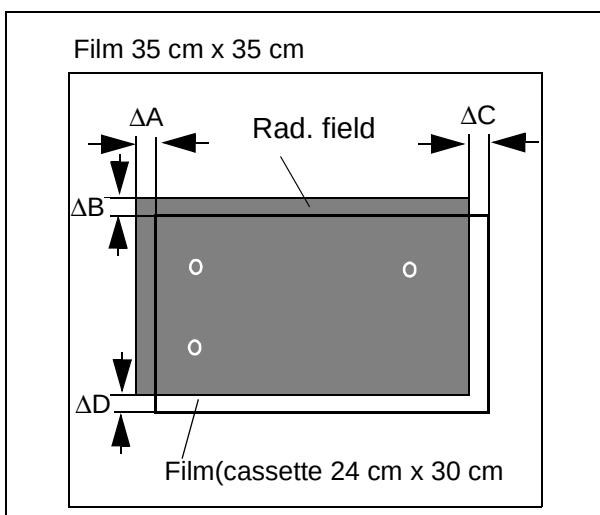


Fig. 5

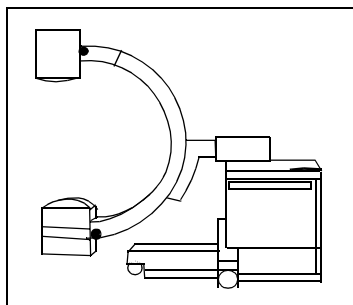
Work sequence:

1. Move the C-arm into the basic position.
2. Attach the cassette holder to the I.I.
3. Load a 24" x 30" cassette with film and insert into the cassette holder.
4. Place a 35 cm x 35 cm film in an opaque envelope and attach the envelope to the center of the film cassette with adhesive tape.
5. In addition, place three washers on the opaque envelope and attach them with adhesive tape.
All three washers must be located within the 24 cm x 30 cm cassette.
6. Expose both films.
7. Develop the films.
8. Place the films one on top of the other.
9. Calculate the deviations.
10. Enter the deviations in the corresponding table.
11. Repeat items 3 through 8 for the C-arm "left" and the C-arm "right" position (Fig.7).

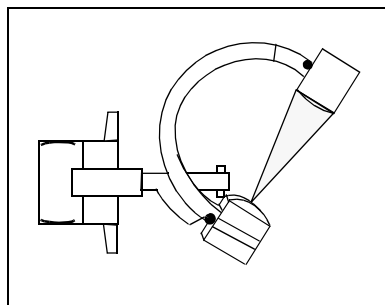


SID' (source film distance) 85.9 cm

Basic position



C-arm to the left,
Tube assembly at stop
(top view)



C-arm to the right,
Tube assembly at stop

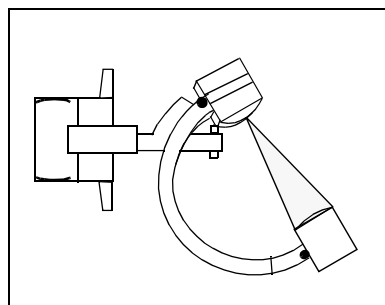


Fig. 6

C-arm basic position

Shading	ΔA	+	ΔC	=	 mm	(must be < 25 mm) (3% of the SID)				
	ΔB	+	ΔD	=	 mm	(must be < 25 mm) (3% of the SID)				
	ΔA	+	ΔB	+	ΔC	+	ΔD	=	 mm	(must be < 34 mm) (4% of the SID)

C-arm to the left, tube assembly at stop

Shading	ΔA	+	ΔC	=	 mm	(must be < 25 mm) (3% of the SID)				
	ΔB	+	ΔD	=	 mm	(must be < 25 mm) (3% of the SID)				
	ΔA	+	ΔB	+	ΔC	+	ΔD	=	 mm	(must be < 34 mm) (4% of the SID)

C-arm to the right, tube assembly at stop

Shading	ΔA	+	ΔC	=	 mm	(must be < 25 mm) (3% of the SID)				
	ΔB	+	ΔD	=	 mm	(must be < 25 mm) (3% of the SID)				
	ΔA	+	ΔB	+	ΔC	+	ΔD	=	 mm	(must be < 34 mm) (4% of the SID)

If the deviations are within the given tolerance, no additional tests are necessary.

7.2 Center cassette to radiation field

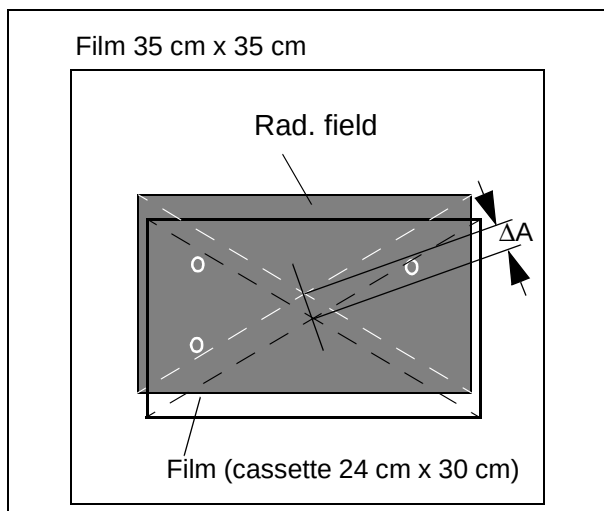


Fig. 7

Work sequence:

1. Use the film pairs already exposed (C-arm in basic position, C-arm to the right and C-arm to the left) to evaluate the center deviation.
2. Place the film pairs one on top of the other.
3. Mark the geometric center of the 24 cm x 30 cm film.
4. Mark the geometric center of the radiation field.
5. Calculate the deviation.

C-arm basic position:

$\Delta = \dots\dots\dots$ mm (must be < 17mm), (2% of the SID)

C-arm to the left, tube assembly at stop

$\Delta = \dots\dots\dots$ mm (must be < 17mm), (2% of the SID)

C-arm to the right, tube assembly at stop

$\Delta = \dots\dots\dots$ mm (must be < 17mm), (2% of the SID)

If the deviations are within the given tolerance, no additional tests are necessary.

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Technical data for DHHS components

In accordance with Federal Radiation Performance
Standards 21 CFR Subchapter J Paragraph 1020.30 (h)

X-Ray Controls and Generators

Nominal line voltage:	Rated line voltage:	Line-voltage- regulation:	Maximum line current:
100 V	$\pm 10\%$	12%	28 A
120 V	$\pm 10\%$	8%	24 A
127 V	$\pm 10\%$	7%	22 A
230 V	$\pm 10\%$	5%	12 A
240 V	$\pm 10\%$	5%	12 A

Technique factors for maximum line current:

110 kV_p tube voltage, 13 mA tube current

Generator ratings:

Fluoroscopy:	110 kVp maximum voltage, 5 mA maximum current		
Radiography:	Duty cycle:	1:60	
		- 40 kV/20 mA	
		- 110 kV/13 mA	

Maximum deviations

Radiography

Tube voltage:	$\pm 10 \%$
accuracy of mAs-product:	$\pm 10 \%$ ± 0.2 mAs

Fluoroscopy

Tube voltage:	$\pm 10 \%$
Tube current:	$\pm 8 \%$ ± 0.1 mA
Fluoroscopy timer:	0 to 5 min. tolerance 1 digit (6 sec)

Basic measurement used

Peak tube potential:	PTW-Nomex (2 filter method)
Tube current:	by using RMS-multimeter
mAs-product:	PTW-Nomex

Tube Housing Assemblies

Maximum rated peak tube potential:	110 kV _p
Leakage technique factors:	110 kV _p /5.0 mA
Minimum filtration permanently in the useful beam: obtained at:	3 mm Al equivalent 80 kV _p

Cooling curves

Tube housing cooling curve:	See Operator's Manual
Tube rating charts:	See Operator's Manual

Definitions of the measurement bases of technique factors**Exposure time tube current product:**

Measured in the mA-measuring pins D1.X39-D1.X40 (x97 opened) in the tube current circuit near ground with an mAs-meter (PTW-Nomex or equivalent).

Peak tube potential:

Measurement of kVp at radiography and at fluoroscopy, using PTW-Nomex (2 filter method).

Tube current:

As measured in the mA-measuring pins D1.X39-D1.X40 (x97 opened) in the tube current circuit near ground with an mA-meter (FLUKE 8060 A or equivalent), minus the current flowing through the built-in high-voltage divider of 0.0025 mA/kV_p.

Final visual and function checks

- After completion of all required operations and checks, perform a visual and function check.

For example, ensure that

- moving parts are freely moving
- there is no danger of collision for moving parts
- safety distances are maintained
- all parts are properly secured
- there is no perceptible damage, etc.

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Chapter 0:	Cover sheet was adjusted, Revision level was adjusted accordingly.
Chapter 2: page 2:	Part No. of the "Tube Housing assembly" changed
Chapter 7:	Content adapted

TD SP 2 / Arnold
TD SP 1 / Schlee
SMS Iselin / O'Donnell

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